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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,160	01/20/2004	Mark W. Kroll	A04P1005	3749

36802 7590 01/25/2007
PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/762,160	Applicant(s) KROLL, MARK W.	
	Examiner Kennedy Schaetzle	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,12-17,19,20,22,25 and 28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23,24,26,27,29 and 30 is/are allowed.
- 6) ☒ Claim(s) 1,4,6-10,18 and 21 is/are rejected.
- 7) ☒ Claim(s) 2 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/3/04, 1/20/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the species involving cardioverting/defibrillating and the subspecies involving the use of a third electrode in the right atrium (claims 1-4, 6-11, 18-21, 23, 24, 26, 27, 29 and 30) in the reply filed on November 2, 2006 is acknowledged.

Claims 3, 19 and 20 pertain to the use of a housing as a third electrode and clearly does not belong with the elected species since the applicant has not disclosed the use of a cardiac stimulation device housing located within the right atrium. Inclusion of these claims appears to be in error. Claims 3, 19 and 20 are therefore withdrawn from consideration.

Claim Objections

2. Claim 21 is objected to because of the following informalities: reference to the first pulse lacks antecedent basis. The examiner suggests amending claim 18 to include the word "first" before the word "electrical" on line 7. Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4, 6 and 8-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Valikai (Pat. No. 5,948,014).

Regarding claim 1, Valikai discloses first and second right ventricular electrodes 120, 130 in a bifocal arrangement, a first lead system 160, and a third electrode 110 positioned outside of the right ventricle. While Valikai does not explicitly refer to the use of a power supply and controller structure, such means are necessary and inherently required in order for the implantable cardiac stimulation device to function as disclosed. In any event, those of ordinary skill in the cardiac stimulation art would have clearly recognized the obvious need for such structure as it is ubiquitously required in practically all implantable devices of the type shown in Fig. 1 in order to permit autonomous operation.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valikai in view of Ideker et al. (Pat. No. 5,107,834).

Valikai does not disclose the use of a pair of leads, each lead adapted for carrying one of the first and second electrodes. Ideker et al. disclose an electrode placement configuration that includes two electrodes within the right ventricle and that may consist of a single multi-electrode lead or a plurality of single electrode leads (see col. 4, lines 10-18). Ideker et al. elaborate that both configuration options are known in the art. The decision as to how many leads to employ is clearly one of obvious design dependent upon such factors as desired ease of implant and desired lead/electrode placement flexibility. Artisans of ordinary skill in the cardiac stimulation industry would have therefore considered the limitations of claim 7 to be a matter of obvious design given the teachings of Valikai and Ideker et al..

7. Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (Pat. No. 4,998,975).

Regarding claim 18, particular attention is invited to col. 11, lines 1-7 and col. 17, lines 29-48. Although Cohen et al. are silent as to the use of a metallic housing, the examiner takes Official Notice that metallic defibrillator housings are old and well-known by those of ordinary skill in the cardiac defibrillator art. Metals allow for a mechanically strong, biocompatible, hermetic and easily manufactured medical housings. Such

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conductive housings also permit greater stimulation/shock flexibility without the need for additional leads by permitting the housing itself to be used as an electrode as is old and well-known in the art.

Regarding claim 21, Cohen et al. describe a shock pattern employing sequential pulses where a positive polarity pulse is followed by a negative polarity pulse (see col. 17, lines 41-48). The examiner considers such a procedure to produce a biphasic waveform. In any event, biphasic waveforms are old and well-known in the defibrillation art due to their recognized efficiency in reverting fibrillation. To employ an industry standard in the Cohen et al. device to permit relatively lower shock energies to be used in effectively treating the patient would have therefore been considered obvious by those of ordinary skill in the art.

Allowable Subject Matter

8. Claims 2, 11, 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 23, 24, 26, 27, 29 and 30 are allowed.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

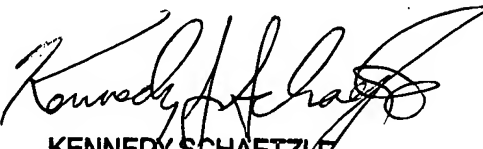
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJS
January 19, 2007



KENNEDY SCHAEETZLE
PRIMARY EXAMINER